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**Notice of Allowability**

Application No.

09/587,662

Examiner

Patrick T. Lewis

Applicant(s)

AU ET AL.

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1623

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to July 6, 2005.
2. ☒ The allowed claim(s) is/are 1,3-24,26-28,42,44,45,47,90,91,97 and 102-128.
3. ☒ The drawings filed on 05 June 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.


Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 08252005.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

  
Patrick Lewis, PhD  
Examiner  
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### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jerry Mueller on August 25, 2005.

The application has been amended as follows:

In claim 1, line 1, after the term "cell", the phrase ---having telomerase activity--- has been inserted.

In claim 6, lines 1-2, the phrase "one or more of the" has been deleted and the phrase --  
-selected from a--- has been inserted therefor.

In claim 42, line 10, after the phrase "to said patient,", the text ---wherein the amount of  
AZT is in a dose of no more than about 0.24 mg/kg/day and the amount of d4T is  
in a dose of no more than about 40 mg/m<sup>2</sup>/day,--- has been inserted.

In claim 47, line 1, the number "45" has been deleted and the number ---42--- has been  
inserted therefor.

In claim 97, line 1, after the term "cell", the phrase ---having telomerase activity--- has  
been inserted.

In claim 97, lines 3-5, the text "being one or more of paclitaxel, docetaxel, vincristine,  
cisplatin, doxorubicin, mitoxantrone, methotrexate, or 5-fluoracil" has been

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deleted and the text ---, said telomere damage-inducing agent being paclitaxel or docetaxel,--- has been inserted therefor.

In claim 97, line 5, after the term "such", the phrase ---telomere damage-inducing--- has been inserted.

In claim 97, lines 8-9, the text "being one or more of AZT, d4T, carbovir, 7-deaza-dGTP, or 7-deaza-dATP" has been deleted and the text ---, said telomerase inhibitory agent being AZT or d4T,--- has been inserted therefor.

In claim 105, lines 1-2, the phrase "one or more of the" has been deleted and the phrase ---selected from a--- has been inserted therefor.

In claim 126, line 1, the term "agent" has been deleted.

Claims 33-35, 46, and 98-101 have been canceled.

### ***Reasons for Allowance***

2. The following is an examiner's statement of reasons for allowance:

Gill US 5,756,537 (Gill) is the closest related prior art. Gill teaches the use of paclitaxel and AZT in the treatment of patients having advanced AIDS-KS. Gill does not teach the AZT dosages used in the treatment. Cheng US 5,869,461 (Cheng) teaches that AZT, because of its potency, is administered in about 20 mg/kg for a typical 70 kg (779 mg/m<sup>2</sup>) patient to treat HIV infections. It would not have been obvious to one of ordinary skill in the art at the time of the invention to employ the use of smaller dosages as instantly claimed.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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***Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Patrick T. Lewis, PhD  
Examiner  
Art Unit 1623

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